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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/086,138	05/28/1998	ROBERT L JAFFE	ETLIP002US	7877

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EXAMINER
GITOMER, RALPH J

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/086,138	Applicant(s) Jaffe
	Examiner Ralph Gitomer	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 24, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-15* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The Response received 7/24/2003 has been entered and claims 1-15 are currently pending in this application.

In view of the arguments presented, the rejection of record under 35 USC 112, second paragraph, is hereby withdrawn.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The addition of ▒a measure of the toxicity of any combination of potentially cytotoxic substances can be obtained▒ to claim 1 is new matter. This feature is not disclosed in the specification as originally filed.

Applicant's arguments filed 7/24/2003 have been fully considered but they are not persuasive.

Applicant argues that the language of the amendment is consistent with the art recognized definition of WET tests and the specification on page 4, line 4.

It is the examiner's position that neither the art recognized meaning nor the specification as originally filed would define a WET test as determining the toxicity of ANY COMBINATION of the substances in the sample, but merely the total sample only. The claim as written would appear to determine the

toxicity of the sample only, not any combination of potentially cytotoxic substances.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaffe.

Jaffe (5,387,508) by the present inventor entitled "Detection of Cytotoxic Agents Using Tetramitus Rostratus" teaches in column 3 first paragraph, ▒The sample may be a liquid, gaseous or solid material, including but not limited to environmental samples or test samples prepared in a laboratory. Samples may be concentrated, or, in the case of solids, suspended in a liquid, prior to testing. Examples of suitable environmental samples include but not limited to water samples including waste water samples, air samples, including industrial stack effluents, and urine specimens of persons exposed to potentially hazardous materials ...▒ See independent claims 1, 6, 16, and 17 where a sample is added to a culture.

All the features of the claims are taught by Jaffe for the same function as claimed.

Applicant's arguments filed 7/24/2003 have been fully considered but they are not persuasive.

Applicant argues that Jaffe does not teach liquid whole effluent samples untreated in any manner are added directly to flagellate cultures.

It is the examiner's position that Jaffe clearly teaches liquid samples added to flagellate cultures where the samples are liquid effluents. Waste water samples are considered effluents. Now, regarding the presently claimed whole effluent sample being directly combined with the flagellates, as argued by Applicant, the specification and claims of Jaffe are understood to teach the sample MAY or MAY NOT be concentrated or diluted. The claims do not recite the sample is or is not concentrated or diluted.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaffe.

Jaffe (5,387,508) by the present inventor entitled "Detection of Cytotoxic Agents Using Tetramitus Rostratus" teaches in column 3 first paragraph, the sample may be a liquid, gaseous or solid material. Various types of whole effluent samples are taught.

The claims differ from Jaffe in that additional flagellates are claimed, dilutions of sample are specified, and filtering is described.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ flagellates other than T. Rostratus because in view of the teachings of Jaffe, one would have a high expectation of success in employing any known flagellate with the requisite qualities taught in the present specification. It is noted that the present specification teaches specific methods and examples only for T. rostratus.

Further, the present claims recite the sample is combined with the culture directly.

In `508 column 3 first paragraph, ※samples may be concentrated, or, in the case of solids, suspended in a liquid, prior to testing.※ It would appear the sensitivity of the test would be dependent upon the concentration of the cytotoxic substances and to dilute or concentrate samples to make them more

suitable for a given test is well known in this art and taught by `508, see column 7 Table 2 which shows various dilutions of a test compound.

Applicant's arguments filed 7/24/2003 have been fully considered but they are not persuasive.

Applicant argues that the claims have been amended to read the sample is a liquid.

It is the examiner's position that Jaffe clearly teaches liquid samples determined for the same function as presently claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button ▒Patent Electronic Business Center▒ for more information.

Ralph Gitomer
Primary Examiner
Group 1651

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